UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, Plaintiff, v. ALEX M. AZAR, III, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No.: 1:19-cv-01672-GLR

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

INTRODUCTION

The Rule undeniably expands both the substance and the enforcement of "conscience protections" under 25 different statutes. Rather than defend this expansion on the merits, HHS denies that the Rule changes the landscape at all and asserts that "the Rule merely implements and clarifies those important preexisting conscience protections enacted by Congress." Def. Opp. 1.[1] This is wrong, as the administration's boast of "new" conscience protections confirms. And it is fatal to HHS's defense of the Rule. HHS expanded conscience protections without statutory authority and without support in the AR. The Rule violates existing federal law protecting patient rights to health care, and it violates constitutional law. The Rule must be vacated in its entirety.

ARGUMENT

I. The Rule Vastly Expands the Scope and Enforcement of the "Federal Conscience Statutes."

HHS considers it "[r]emarkabl[e]" that the City "do[es] not challenge the underlying Federal Conscience Statutes" as part of its APA challenge. Def. Opp. 1. But the very purpose of the APA is to ensure that "*administration* of [Congress's] own statutes" is "judicially confined to the scope of authority granted or the objectives specified." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986) (quoting S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945)).[2] The City challenges HHS's broad new *Rule*, which is neither coterminous with the Federal Conscience Statutes, nor a mere clarification of those narrow, clearly delineated statutes.

[1] The City refers to Plaintiff's Motion for Preliminary Injunction (Dkt. 14-1) as "PI Motion"; Defendant's Opening Summary Judgment Brief (Dkt. 44) as "Def. Br."; Plaintiff's Opening Summary Judgment Brief (Dkt. 50-1) as "Pl. Br."; Defendants' Opposition and Reply (Dkt. 92) as "Def. Opp."

[2] All emphases in the brief are added unless otherwise indicated.

A. The Rule's text clearly expands the Federal Conscience Statutes.

HHS's assertion that the "challenged definitions in the Rule reflect the unambiguous meaning of the terms in the Federal Conscience Statutes" is easily refuted. Def. Opp. 5. As set forth in the City's prior briefing, PI Motion 22-24; Pl. Br. 25-30, and in Section II.C, *infra*, the Rule *expands* the substantive scope of carefully-delineated statutory provisions beyond their longstanding meaning, which providers have relied upon and complied with for decades. Among other expansions, the Rule: (1) permits any worker in the healthcare arena to refuse to perform ordinary job duties with any "specific, reasonable, and articulable connection to furthering" a procedure, no matter how removed; (2) radically expands the list of individuals and entities qualifying as a "health care entity"; (3) expands "referral" to include any communication with a "reasonably foreseeable outcome" of "assist[ing] a person in" obtaining or receiving funding for an objected-to procedure; and (4) curtails healthcare providers' ability to make accommodations for objecting entities. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170, 23,186, 23,263-264 (May 21, 2019); *see also* Def. Opp. Ex. 1 (comment stating that "the proposed regulations *define* particular statutory terms with *commendable breadth*").

The Rule expressly anticipates that it will increase denials of care. In response to comments expressing "concerns about expanding protection to HIV treatment, pre-exposure prophylaxis, and infertility treatment," HHS confirmed that the Rule encompasses such refusals, stating: "In the event that the Department receives a complaint with respect to HIV treatment, pre-exposure prophylaxis, or infertility treatment, the Department would examine the facts and circumstances of the complaint to determine whether it falls within the scope of the statute in question *and these regulations*." 84 Fed. Reg. 23,182; *see also id.* 23,189, 23,205 (HHS would consider refusals to refer LGBT persons or treat gender dysphoria on a "case-by-case basis"). There is ample evidence

in the AR that the expanded definitions will harm LGBTQ individuals' efforts to obtain counseling, PrEP, infertility care, treatments related to gender dysphoria, and HIV treatment. *See*, *e.g.*, Pl Br. 14 n.12.[3]

Facilitating refusals of care to transgender individuals is an *intended* consequence of the Rule. Troublingly, HHS cited as a justification for the Rule *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017), a case in which a transgender man alleged that he had been denied a hysterectomy because of his gender identity.[4] 84 Fed. Reg. 23,176 & n.27. HHS's brief confirms its view that a refusal by a correctional facility worker to provide "hormone therapy to incarcerated transgender persons could potentially relate to the Federal Conscience Statutes." Def. Opp. 19 n.5.

B. HHS previously concluded that the expanded definitions in the Rule were overbroad and inconsistent with the Federal Conscience Statutes.

HHS itself concluded in 2011 that the definitions it now proposes to reinstate were "overbroad in scope" and inconsistent with the intent of the Federal Conscience Statutes. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) (the "2011 Rule"). HHS confirmed that:

> The 2008 Final Rule may have caused confusion as to whether the Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs. The Federal provider conscience statutes were intended to protect health care providers from being forced to *participate in medical procedures* that violated their moral and religious beliefs. They were *never intended*

[3] *See also, e.g.*, Ex. 51 (AR140635 at 140639); Ex. 52 (AR138013); Ex. 53 (AR59389); Ex. 54 (AR106); Ex. 55 (AR6649); Ex. 56 (AR7577); Ex. 57 (AR8890); Ex. 58 (AR9247); Ex. 59 (AR9506); Ex. 60 (AR10053); Ex. 61 (AR135903); Ex. 62 (AR134884); Ex. 63 (AR134797); Ex. 64 (AR136181) This is a sampling of hundreds of individual and organizational comments in the AR concretely identifying how the Rule's expanded definitions will increase denials of necessary health care for LGBTQ individuals.

[4] A California court recently held that Minton alleged a cognizable claim for denial of "full and equal access to health care treatment." *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Sept. 17, 2019) (noting that it is permissible to burden religious exercise where necessary to ensure full and equal access to medical treatment). *See also* Ex. 31 (AR135450) (discussing *Minton*).

> *to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable*.

Id. at 9973-74. HHS has given the Court no reason to turn a blind eye to that reasoned conclusion.

C. The Rule imposes new compliance and enforcement provisions.

Finally, the Rule vastly expands OCR's enforcement authority. The new Rule gives OCR: (1) "discretion in choosing the means of enforcement"—including for noncompliance with the *new* assurance and certification requirements; (2) authority to conduct "compliance reviews" regardless whether a complaint has been filed; and (3) authority to investigate complaints "whether or not the particular complainant is a person or entity protected by Federal conscience and anti-discrimination laws." 84 Fed. Reg. 23,221-222; 45 C.F.R. § 88.7(b)(c). The Rule allows OCR, in "coordination with the funding component," to terminate not only the federal award at issue, but *all* federal funds administered by HHS, 84 Fed. Reg. 23,272; 45 C.F.R. § 88.7(i)(3).

In short, HHS's assertion that the Rule does not "meaningfully differ[] from the Federal Conscience Statutes" and merely "applies existing procedures for administering federal awards," Def. Opp. 1, 8, does not withstand even mild scrutiny.

II. HHS Lacks Statutory Authority for its Legislative Rulemaking.

As set forth above, HHS has engaged in *substantive, legislative* rulemaking—not mere administration. The Rule purports to interpret and implement the Church, Coats-Snowe, and Weldon Amendments, the ACA, and approximately 20 other statutes. 84 Fed. Reg. 23,170. But HHS identifies no legislative authority for expanding the scope of the Federal Conscience Statutes or imposing new substantive compliance requirements and enforcement mechanisms. Because HHS's rulemaking lacks authority, no deference is due. *See, e.g.*, *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation

of administrative authority."). Even if HHS had authority to expansively interpret the Federal Conscience Statutes—as a matter of law it does not—its definitions are unreasonable.

A. HHS's "housekeeping" and "monitor[ing]" authority does not authorize substantive expansion of the Federal Conscience Statutes.

HHS invokes 5 U.S.C. § 301 and other "regulations regarding the administration of funding instruments" as its authority for "complaint investigation *or defining relevant terms*." Def. Br. 21; Def. Opp. 3. But Section 301 "authoriz[es] what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'"[5] *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979). The Supreme Court distinguished regulating "the way in which requests for information are to be dealt with" from "claim[ing] authority to withhold information." *Id.* at 310 n.41 (citing legislative history). The Rule goes well beyond delegating authority to receive complaints: HHS redefines the scope of the Federal Conscience Statutes and arrogates to itself the authority to impose draconian "consequences" for noncompliance with those new, unauthorized conditions. Def. Opp. 4. While the 2011 Rule addresses "the way in which [complaints] are to be dealt with,"[6] the 2019 Rule's expansion of enforcement authority is akin to "authority to withhold" and, as such, is far outside the scope of housekeeping. *Chrysler Corp.*, 441 U.S. at 310 n.4.

HHS tries to justify the Rule by arguing that it is "required under the Federal Conscience Statutes to apply certain conditions to federal awards."[7] Def. Opp. 4. But the Rule doesn't apply existing conditions—it establishes entirely *new* "conditions" with no basis in the Federal

[5] The Rule is plainly "substantive" under the APA. It has all the "hallmark[s] of a legislative rule": it underwent notice and comment, and its "interpretation of [key statutory terms] as well as the compliance procedures impose obligations on covered entities." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 46 (D.D.C. 2014) (explaining why rule is legislative, not interpretive).

[6] The City is not challenging OCR's authority to receive complaints. Def. Opp. 3.

[7] The City did not "abandon" but rather expressly addressed the argument that HHS cannot rely on grant and funding authority for the Rule. Def. Opp. 3. *See* Pl. Br. 23.

Conscience Statutes. HHS cannot invoke funding regulations to alter the substantive parameters of Federal Conscience Statutes.

B. HHS lacks any other authority to expand the Federal Conscience Statutes.

HHS contends that "several statutory provisions explicitly grant HHS sufficient regulatory authority here" and cites three provisions of the ACA (42 U.S.C. §§ 18023, 18041, 18113), two narrow provisions of the Social Security Act (42 U.S.C. §§ 1302, 1315a), and one provision of the Public Health Services Act (PHSA) regarding certification of laboratories (42 U.S.C. § 263a). As HHS acknowledges, "[t]he great majority of the Federal Conscience Statutes that the Rule implements, of course, are not part of the ACA." Def. Br. 31. *None* of the laws HHS invokes grant it authority to interpret the Church, Coats-Snowe, or Weldon Amendments at the heart of the Rule.

HHS says that *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28 (D.D.C. 2014) ("*PRMA*"), does not apply because in that case the agencies "lacked authority under any of the statutes to which they pointed." Def. Opp. 5. That is wrong. The court in *PRMA* considered a scenario similar to the one here—where "HHS has strung together … specific grants of authority" from different statutory provisions, which the court found "do not authorize the orphan drug rule implemented." 43 F. Supp. 3d at 39. The court rejected a "limited grant of rulemaking authority in *an entirely different statute*" as the basis for the rule. *Id.* at 40 (emphasis in original). The court also considered express delegations of authority under the two statutes at issue—the PHSA and the 340B program. It found the first lacking because it related to "administration … not the *implementation* of the [PHSA]" and found the second lacking because it was related to "resolving disputes." *Id.* at 39, 42-43 (emphasis in original). The court invalidated the Rule at *Chevron* step one. *Id.* at 45.

The rulemaking authority upon which HHS relies for this Rule is even less compelling than that in *PRMA*. ACA Section 1553, which relates to assisted suicide, simply designates OCR "to receive complaints of discrimination based on this section." 42 U.S.C. § 18113(d). This is exactly the kind of "administrative" authority *PRMA* rejected as a basis for substantive rulemaking such as redefining key statutory terms.[8] 43 F. Supp. 3d at 39. And Church, Coats-Snowe, and Weldon delegate *no* authority to HHS. *PRMA* expressly rejected HHS's attempt to use 42 U.S.C. § 1302 (governing Medicare and Medicaid) to issue rules pursuant to the PHSA. 43 F. Supp. 3d at 41 & n.13. HHS cannot recycle that failed effort here to expand the substantive provisions of Church, Coats-Snowe, Weldon, and the ACA.[9]

Finally, HHS has no support for its conclusory assertion that it has "implicit" authority to redefine conscience protections in the Federal Conscience Statutes. Def. Opp. 6. HHS identifies no "gap left, implicitly or explicitly, by Congress" in the self-enforcing, narrowly delineated statutes. *Id.* (quoting *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)). In fact, HHS admitted there are none. Def. Br. 50 (Federal Conscience Statutes "clearly provide[] unambiguous notice to funding recipients of the Statutes' anti-discrimination provisions."); Pl. Br. 22-25. The circumstances

[8] *Gonzales v. Oregon,* 546 U.S. 243 (2006) is also instructive. There the Supreme Court considered a rulemaking under the Controlled Substances Act, which *expressly* gave the Attorney General rulemaking power in "two specific areas"—"dispensing of controlled substances" and rules "necessary and appropriate for the efficient execution of his functions under this chapter." *Pharm. Research*, 43 F. Supp. 3d at 37 (quoting *Gonzales*, 546 U.S. at 259). The Supreme Court vacated a rule defining "legitimate medical purpose" not to include assisted suicide under the CSA, on the ground that the CSA did not grant "this broad authority to promulgate rules." *Id.* at 38 (quotation omitted). Here, HHS identifies no express delegation of authority to interpret or implement Church, Coats-Snowe, or Weldon.

[9] HHS does not even attempt explain how the other narrow and largely administrative provisions it cites give it authority to "implement[]" and "interpret" the substantive conscience protections. For example, HHS does not explain how 42 U.S.C. § 18041, requiring HHS to establish exchanges under the ACA, gives it authority to expand substantive conscience protections. *See* Def. Opp. at 4 n. 1. It does not grant that authority under the ACA, and it certainly does not grant authority as to 20 other statutes in the Rule, including Church, Coats-Snowe, and Weldon.

present in *Morton*—a 140-year history of agency promulgation of rules and policies and an "explicit[]" delegation of authority to the Secretary—are manifestly absent here.

C. HHS's definitions are unreasonable.

Because HHS lacks any authority for "interpreting" the statute, the Rule fails at *Chevron* step one, and there is no need to assess reasonableness. *PRMA*, 43 F. Supp. 3d at 45. Even where authority exists, however, an agency interpretation that is "inconsistent with the design and structure of the statute as a whole does not merit deference." *Util. Air Regulatory Grp. v. E.P.A.*, 573 U.S. 302, 321 (2014). HHS's definitions are incompatible with the text of the statutes it purports to interpret and with the robust legislative framework protecting conscience objections *and* patient rights to nondiscriminatory health care—*not* elevating the former over the latter.

Church, Coats-Snowe, and Weldon are narrowly tailored to address specific procedures—abortion, sterilization, and assisted suicide—in specifically delineated contexts, e.g., in Church Amendment Section (d), behavioral and biomedical research.[10] Pl. Br. 26-30. They are "unambiguous," Def. Br. 50, and Congress evinced no intent to read them "expansively."

HHS ignores, for example, Sen. Church's statement that the "amendment is meant to give protection to the *physicians, to the nurses, to the hospitals themselves, if* they are religious affiliated institutions." 119 Cong. Rec. S9595 (Dec. 22, 1973). Nothing in Church (or Weldon, or Coats-Snowe) suggests Congress intended to allow any employee in the healthcare arena to opt out of providing care for individuals based on any religious or moral objection. Yet the Rule's definition

[10] Contrary to HHS's assertion that the Church Amendments cover "a broad range of activity," Def. Opp. 9, the legislative history confirms that Church (d), 42 U.S.C. § 300a-7(d), applies in narrow circumstances. Church (c) and (d) were added in 1993 when Congress passed The National Research Act, Public Law 93-348, and were accepted by the Conference Committee with the express limitation that they apply "only to entities that receive grants or contracts for biomedical or behavioral research under programs administered by the Secretary." H.R. Conf. Rep. 93-1148.

of "assist in the performance" authorizes exactly that. *See* 84 Fed. Reg. at 23,186 ("Scheduling an abortion or preparing a room… are necessary parts of the process" and, therefore, constitute "assistance"); *id.* 23,205 (covering treatment for gender dysphoria). As set forth in Section IV.B *infra*, HHS in 2011 concluded that the Federal Conscience Statutes did not allow this. HHS has not justified its new reading of legislative intent.

HHS's new definition of "health care entity" is an unjustified expansion of an *explicitly defined term*. Even if, as HHS contends, Congress's lists are "non-exhaustive," HHS's additions must be consistent with the others in the list. *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010). HHS does not and cannot explain how expanding the list from "physicians" and "health care professionals" to ***all*** "health care *personnel*," and adding pharmacists,[11] 84 Fed. Reg. 23,264, is consistent with carefully-calibrated lists in Weldon, Coats-Snowe, and the ACA. *Cf. Samantar*, 560 U.S. at 319 ("careful calibration of remedies among the listed types of defendants suggests that Congress did not mean to cover other types of defendants never mentioned in the text.").

HHS's Rule creates a single new definition of "discrimination" to be employed across 25 different statutes, which govern diverse, limited contexts. Def. Opp. 10. As discussed in Section III.B, *infra*, the definition, which contains no "undue hardship" exception, *directly* conflicts, for example, with ACA Section 1303(c)'s prohibition on interfering with the employer-employee relationship under Title VII. In defending the sweeping definition, HHS *emphasizes* that there is "no universal definition of discrimination that governs all federal statutes" and that the definition contains a "*non-exhaustive list*" of scenarios. Def. Opp. 9-10, 12 (emphasis in HHS brief). That

[11] The National Community Pharmacist Association itself noted that "pharmacists are not the intended provider" under the statutes and urged OCR to rescind the Proposed Rule as in excess of statutory authority." Ex. 65 (AR147879).

only *highlights* the overbreadth. That *additional* scenarios may constitute discrimination makes the definition more unreasonable and impedes providers' ability to comply.

The Rule's expansion of the term "referral" from its understood technical meaning in the healthcare context to a far more sweeping definition also lacks justification.[12] HHS's refrain that the definition "consists of a *non-exhaustive list* of items that *may* constitute 'referral,'" Def. Opp. 12, is no restriction at all and no comfort to providers attempting to comply.

Even if HHS had the authority to issue these expansive definitions, they cannot be squared with the text of the statutes or Congress's intent.

III. The Rule Violates Existing Federal Law Protecting Patients' Rights.

A. ACA Section 1554 prohibits HHS from "promulgat[ing] any regulation" that "creates any unreasonable barriers," or "impedes timely access" to health care.

Notably, HHS's opposition *does not dispute* that the Rule creates "unreasonable barriers" and "impedes access" under ACA Section 1554. 42 U.S.C. § 18114. Instead, HHS rejects (and characterizes as "extraordinary") the assertion that Section 1554, which specifically addresses *HHS*'s ability to "*promulgate any regulation*" restricts HHS's authority to issue the Rule. Def. Opp. 13. HHS claims that interpreting Section 1554 to mean what it says would "render meaningless … many Federal Conscience Statutes" and "mean that HHS could not put any restrictions on Medicare or Medicaid funding through regulations." *Id.* This parade of horribles lacks any basis in reality.

[12] The medical regulatory backdrop makes clear that Congress intended the word "referral" to have its normal meaning in the healthcare setting—for a provider to direct a patient to another provider. *See, e.g.*, Medicare.gov, *Glossary-R*, https://www.medicare.gov/ glossary/r (last visited Oct. 2, 2019) (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); Ctrs. for Medicare & Medicaid Serv., *Glossary*, https://go.cms.gov/2LN4RE1 (last visited Oct. 2, 2019) ("referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services.").

First, as the City explained, Section 1554 does not affect "Federal Conscience *Statutes*"—it speaks only to HHS's *regulatory* authority. Pl. Br. 19. *Second*, Section 1554 limits only "unreasonable" barriers and, thus, does not limit all restrictions under Medicare, Medicaid, or any other regulatory authority. *Third*, even if Section 1554 were limited to regulations under the ACA, as HHS argues, Def. Br. 31, it would limit HHS's authority here: HHS invokes as its *primary* authority for the Rule several provisions of the ACA, including Sections 18023, 18041, and 18113. Def. Opp. 5. As set forth in Section II.B, *supra*, these sections do not grant HHS authority to expand other Federal Conscience Statutes, a "great majority" of which are not the ACA. Def. Br. 31. But HHS certainly cannot simultaneously invoke authority under the ACA *and* ignore Section 1554's restriction on its authority to "promulgate any regulation" restricting access to care.

Nor does Section 1303(c)(2) nullify Section 1554. Section 1303(c)(2) confirms that the ACA shall not be "construed to have any effect on *Federal laws* regarding—(i) conscience protection." Section 1554 does not restrict "Federal law" regarding conscience protection—it governs rulemaking. There is no need to look at the ACA's legislative history to conclude that Section 1303 speaks to legislation, whereas Section 1554 speaks to regulation. The plain text—Section 1303(c) referring to "Application of State and Federal laws regarding abortion"[13] and Section 1554 referring to HHS authority "promulgate any regulation"—answers the question.

B. The Rule conflicts with ACA Section 1303(c) and EMTALA.

Far from giving HHS free reign to expand conscience protections, as HHS contends, Def. Opp. 4, Section 1303 *restricts* HHS's authority under the ACA and confirms that the Rule is contrary to Federal law. Section 1303 states that it shall not "alter the rights and obligations of

[13] *United States v. Mitchell*, 39 F.3d 465 (4th Cir.1994) analyzed the term "contrary to law," not the term "State and Federal laws," and is therefore inapposite.

employees and employers under title VII of the Civil Rights Act of 1964" or "relieve any health care provider from providing emergency services … including … [as required by] EMTALA." The Rule runs afoul of both prohibitions.

The Rule's expansive definition of "discrimination" (for which HHS's only purported rulemaking authority is the ACA) does exactly what Section 1303 forbids—it "alter[s] the rights and obligations of employees and employers under title VII" by eschewing any "undue hardship" exception to an employer's obligation to make accommodations. The Federal Conscience Statutes are silent on the issue of "undue hardship." HHS is not free to expand those statutes under the authority of the ACA in a manner that "alter[s] the rights and obligations of employees and employers under title VII."

The Rule also impermissibly "relieve[s] any health care provider from providing emergency services as required by State or Federal law, including [under EMTALA]" in violation of Section 1303(d) and EMTALA itself. As the Fourth Circuit has stated, EMTALA's "core purpose is to get patients into the system who might otherwise go untreated and be left without a remedy because traditional medical malpractice law affords no claim for failure to treat" and "to deal with the problem of patients being turned away from emergency rooms for non-medical reasons." *Bryan v. Rectors & Visitors of Univ. of Virginia*, 95 F.3d 349, 351 (4th Cir. 1996). The Rule runs counter to this "core purpose" by authorizing an individual to "fail[] to treat" an individual in an emergency situation based on an objection to that person's identity or the treatment sought. A violation of EMTALA would result if even a single ambulance driver refused care—and the Rule confirms that "EMTs and paramedics are treated like other health care professionals under this definition." 84 Fed. Reg. 23,188. HHS's refusal to treat emergencies differently creates

an irreconcilable, non-hypothetical conflict between EMTALA and the Rule. HHS has offered no explanation of how it could apply EMTALA and the Rule harmoniously.

This is a problem borne of the *Rule*'s expanded definition of "assist in the performance" and "discriminate and discrimination," which together expand conscience protections to individuals even tangentially involved in a procedure and prevent providers from finding reasonable accommodations. It is not, as HHS contends, a conflict between EMTALA and the Federal Conscience Statutes themselves.

C. The Rule conflicts with ACA Section 1557.

HHS incorrectly reads Section 1303(c)(2) to elevate "federal conscience protections" and to nullify Section 1557's non-discrimination mandate—which is not at all what Section 1303(c)(2) says. Section 1303(c) requires no effect on "Federal laws regarding conscience protection" *and* "No effect on Federal civil rights law." 42 U.S.C. § 18023. HHS's insistence that federal conscience protections (statutory or regulatory) trump all other statutory protections against discrimination in health care is the central flaw in the Rule and a reason to vacate it.

IV. HHS's Unexplained Policy Reversal and Disregard for Patients' Rights Was Arbitrary and Capricious.

HHS's argument that the Rule is not arbitrary and capricious is replete with platitudes—for example, HHS "provided 'a rational connection between the facts found and the choice made [and] supported each challenged aspect of the Rule with sound and detailed reasoning." Def. Opp. 15-16. These assertions are unsupported by anything in the AR and rely heavily on HHS's now-discredited assertion that the change in policy is justified by the "recent, documented instances of alleged and demonstrated conscience discrimination." *Id.* at 16.

A. The Administrative Record refutes HHS's justification for the Rule.

HHS's attempt to rehabilitate its reliance on an increase in complaints as a justification for the Rule fails. HHS asserts that a "sizeable number of complaints did implicate the relevant statutes" and cites a total of *eight* complaints, bringing the total up to, at most, 11 complaints in the AR. Def. Opp. at 18 n. 4. Again, this falls far short of what HHS represented as "the reasons for this rule"—that "[d]uring FY 2018 … OCR received ***343 complaints alleging conscience violations***." 84 Fed. Reg. 23,229. HHS cannot escape that it "offered an explanation for its decision that runs counter to the evidence before the agency," rendering the Rule arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins*., 463 U.S. 29, 43 (1983); *accord Casa De Maryland v. U.S. Dep't of Homeland Sec.,* 924 F.3d 684, 703 (4th Cir. 2019) ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself."). The disconnect between HHS's justification and the AR warrants vacating the Rule.

B. HHS's contention that the 2011 Rule was inadequate or confusing is contrary to the Administrative Record.

While an agency is entitled to "rebalance old facts to arrive at the new policy," it is not entitled to "ma[k]e factual findings directly contrary to the [prior rule] and expressly rel[y] on those findings to justify the policy change." *Organized Vill. of Kake v. U.S. Dep't of Agric*., 795 F.3d 956, 968 (9th Cir. 2015). HHS does not even argue that it is giving more weight to particular facts. It instead asserts that the 2011 Rule "created confusion." Def. Opp. 16. That is the opposite of HHS's conclusion in 2011 that the "2008 Final Rule may have caused confusion as to whether the Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs." 76 Fed. Reg. 9973-74.

HHS's few citations to the AR do not support this 180-degree policy change. Exhibit 1 cites HHS's own now-discredited assertion of a "rise in the rate of complaint filings." Def. Opp.

Ex. 1 [Dkt. 92-1] ("The preamble [to the NPRM] provides ample documentation of the record of violations of the federal conscience statutes in the United States."); *see also id.* Ex. 4 [Dkt. 92-4] (claiming, without support, a "sharp increase in administrative complaints over the past year"). *Cf. id.* Ex. 2 [Dkt. 92-2] (citing to instances of alleged violation of conscience protections that largely occurred before 2011). Indeed, one of HHS's cited comments *supports* the 2011 Rule's recognition that conscience protections should not facilitate denials of services based on "discomfort" or "animus." *Id.* Ex. 5 [Dkt. 92-5] at 2 ("Every individual seeking health care should always be treated with kindness and respect, and failure to do so because of discomfort with or animus against an individual on any basis is unacceptable."). Yet, as set forth in Section IV.C, *infra*, the Rule ignores this important concern entirely. Because HHS acted arbitrarily and capriciously in "chang[ing] course without any explanation for why [its earlier] analysis was faulty," the Rule must be set aside. *Casa De Maryland,* 924 F.3d at 705.

HHS also has no response to the City's argument that it failed to consider that "its prior policy has engendered serious reliance interests." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015); Pl. Br. 12. HHS cites to a line-item in the cost-benefit analysis regarding familiarization, Def. Opp. 17, but nowhere (not in the Rule or in its briefs) even acknowledges the numerous comments regarding how healthcare entities have structured their programs to accord with the existing legislative and regulatory framework for conscience protections. *See, e.g.* Pl. Br. 12 n.10.[14] That failure renders the Rule arbitrary and capricious. *Casa De Maryland*, 924 F.3d at

[14] *See also, e.g.*, Ex. 66 (AR32771) (City of Miami opposing rule that "would broadly expand opportunities for healthcare workers to refuse to participate in certain medical procedures on the basis of a moral or religious objection," and noting that Proposed Rule is estimated to "impact somewhere between 364,640 to 571,412 entities including public and private hospitals, specialty hospitals, …youth services, shelters, nursing and hospice facilities, offices of mental health practitioners, and family planning centers[.]").

705 ("Although the government insists that Acting Secretary Duke considered these interests in connection with her decision to rescind DACA, her Memo makes no mention of [the hundreds and thousands of people [who] had structured their lives on the availability of deferred action].").

C. HHS improperly disregarded concrete evidence of harm to patients from discrimination.

When a Court considers an agency's stated reasons for a decision in conducting arbitrary and capricious review, it must satisfy itself that the agency "consider[ed] *and respond[ed]* to significant comments received during the period for public comment." *Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602 (D. Md. 2019) (citing *Perez*, 135 S. Ct. at 1203). Conclusory statements that HHS considered all the comments are not enough, where, as here, "when it came to explaining [the changed policy] the Department said almost nothing." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2120 (2016).

HHS's opposition focuses entirely on how the Rule would supposedly encourage more religious healthcare providers to "enter the health care field" (a proposition not supported by serious evidence) and does not even acknowledge comments about how the Rule will increase discriminatory denials of care. Def. Opp. 19-21. If HHS had explained *why* it prioritized religious rights over the rights of patients to uninterrupted, non-discriminatory care, there might have been a genuine question whether that explanation was "satisfactory" under the APA. *Casa de Maryland*, 924 F.3d at 703. But HHS did not provide *any* explanation. It ignored the problem entirely. This is quintessentially arbitrary and capricious.

The 2011 Rule placed the issue of discrimination against patients front and center. *See* 73 Fed. Reg. 9974 (Federal Conscience Statutes were "never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."). HHS's failure to address this problem is even more arbitrary in

light of the agency's "lack of reasoned explication for a regulation that is inconsistent with the Department's longstanding earlier position." *Encino Motorcars*, 136 S. Ct. at 2120–21.

V. The Rule Violates the Establishment and Spending Clauses.

A. The City's constitutional claims under the APA are justiciable.[15]

HHS wrongly argues that the City's constitutional claims are unripe in the absence of agency enforcement action. With respect to the Spending Clause violation, the injury here is the unlawful coercion inherent in the decision whether to accept federal funds in the first place. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581-82 (2012) (threatened loss is "economic dragooning" that leaves no real option but to acquiesce). The Rule's new, draconian clawback remedy means that accepting funding—under greatly expanded conditions—might result in having to repay monies already spent, thus endangering not just future *federal* funding but also funds from other sources. That HHS might decline to enforce to the fullest extent does not offset the risk associated with the *new* coercive conditions attached to such a significant part of the City's budget.

HHS argues that review of the City's Establishment Clause claim must await enforcement to determine how the definition of discrimination will be applied. But the Rule's expansive definition, *see* Section II.C, *supra*, places unprecedented limits on providers' ability to accommodate employees while ensuring patient health and safety. The Rule forbids almost any employment action toward religious objectors other than absolute obeisance. The City must grapple with this reality now. The constitutional claims are thus ripe for review.

[15] HHS is wrong that the Court cannot consider declarations filed in support of the City's suit. HHS's challenge to the City's standing, while meritless, not only authorizes, but requires the City to "supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review." *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). The declarations establish standing by showing how the Rule will both harm the City directly and interfere with the City's ability to protect the public health.

B. The Rule Violates the Spending Clause.

In an attempt to rescue the Rule from Spending Clause prohibitions, HHS resorts to its fallback that the Rule merely mirrors what the Statutes already require. As explained in Section I, *supra*, nothing could be further from the truth. As particularly relevant here, the threat of complete loss and clawback of federal funding—even funding unrelated to conscience objections—renders the expanded conditions unconstitutionally coercive. The expanded enforcement is a transformation "in kind, not merely degree." *See NFIB*, 567 U.S. at 582-83 (finding irrelevant that Congress called the program a "modification" when it was in effect a "new program").[16]

C. The Rule violates the Establishment Clause.

i. The Rule imposes the burdens of objecting employees' religious beliefs on third parties, including the City, providers, and patients.

HHS in effect contends that the Establishment Clause tolerates religious accommodations no matter the material burdens and costs they impose on third parties. Def. Opp. 28. That position is irreconcilable with Supreme Court precedent.[17] *See* Pl. Br. 35–36 & n.25. The question is not

[16] Courts also permit plaintiffs to submit extra-record evidence in support of their constitutional claims under § 706(2)(B). *See, e.g.*, *Tafas v. Dudas*, 530 F. Supp. 2d 786, 802 (E.D. Va. 2008) ("When a court is reviewing the constitutional validity of agency action pursuant to 5 U.S.C. § 706(2)(B), it should make 'an independent assessment of a citizens' claim of constitutional right.") (quoting *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979)); *Nat'l Med. Enters., Inc. v. Shalala*, 826 F. Supp. 558, 565 n.11 (D.D.C. 1993) (allowing plaintiffs to submit additional declaration not in administrative record); *Rydeen v. Quigg*, 748 F. Supp. 900, 906 (D.D.C. 1990) (same). *Fort Sumter Tours, Inc. v. Babbitt*, 66 F.3d 1324 (4th Cir. 1995), cited by HHS, Def. Opp. 31–32, recognizes but that there may be circumstances to justify expanding the record or allowing discovery. *Babbitt* did not involve a constitutional challenge under Section 706(2)(B) of the APA. The declarations provide highly relevant merits evidence. The declarations here demonstrate a far greater injury to the City than the 20 percent loss of funding in *NFIB*.

[17] The cases on which HHS relies do not support its position. Justice Kennedy's concurrence in *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*—joined by no other Justice—acknowledges that "[t]here is a point … at which an accommodation may impose a burden on nonadherents so great that it becomes an establishment," and explains that the issue did not arise in the case. 512 U.S. 687, 725 (1994) (Kennedy, J., concurring). In *Gillette v. United States*, 401 U.S. 437, 448-54 (1971), the Court held only that the statute did not violate the Establishment Clause by treating similarly situated religious objectors differently. *Gillette* did not present the question whether the

whether courts must "take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries," *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005)—they must. The question is when does an accommodation become an unconstitutional religious preference. This Court need not identify that precise threshold because, as the City has shown, Pl. Br. 38, the burdens in this case are far more severe than those that required invalidation in, for example, *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989), and *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985).

ii. The Rule impermissibly prefers religion over other beliefs.

The Rule violates the Establishment Clause because its "ostensible object" and primary effect are to advance religion. *McCreary County. v. ACLU of Ky.*, 545 U.S. 844, 860, 863 (2005). That is so whether or not the Rule uses some religiously neutral language or purports to treat religious and nonreligious objectors alike. *See, e.g.*, *id.*; *Kiryas Joel*, 512 U.S. at 699 ("identification here of the [favored] group . . . in terms not expressly religious" "does not end" Court's inquiry into whether challenged statute afforded unconstitutional preference to religious group); *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531–33 (1993) (Establishment Clause "forbids subtle departures from neutrality"). Here, the "departures from neutrality" are not subtle. HHS boasts of them:

> The rule will promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights . . . . 'It is the duty of every man to render to the Creator such homage, and such only, as he believes to be acceptable to him.'"

84 Fed. Reg. 23,246. That the Rule recognizes some "non-religious beliefs" as well as the favored religious ones, Def. Opp. 28, is no defense.

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exemption impermissibly harmed any identifiable nonbeneficiary, which it didn't. *See, e.g.*, Geddicks & Van Tassell, *RFRA Exemptions from the Contraception Mandate: An Unconstitutional Accommodation of Religion*, 49 Harv. C.R.–C.L. L. Rev., 343, 367 & n.114 (2014). Finally, *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 339 (1987), underscores this constitutional rule. Pl. Br. 39 & n.27.

If the government, in prioritizing religion, is not removing a burden on religious exercise of its own making, it impermissibly favors and elevates one person's religious beliefs over others' beliefs and other rights. *Caldor*, 472 U.S. at 709–10. Contrary to HHS's suggestion, Def. Opp. 30, Title VII complies with this principle and highlights why the Rule does not: Title VII's religious-accommodation provision ameliorates burdens on employees' religious exercise imposed by the statute's nondiscrimination provisions. And it avoids materially burdening nonbeneficiaries by not requiring accommodations that impose more than a "*de minimis* cost" to the employer. *Trans World Airlines v. Hardison*, 432 U.S. 63, 81, 84 (1977); *E.E.O.C. v. Firestone Fibers & Textiles Co.*, 515 F.3d 307, 312–14 (4th Cir. 2008). The Rule, in contrast, impermissibly privileges some employees' religious beliefs over others and demands that employers bear the costs of religious accommodation without exception and without regard to burden on the employer.

VI. The Court Should Vacate the Rule in Its Entirety.

The deficiencies in the Rule pervade the entire Rule and require vacating it in its entirety. As a general matter, Courts "do not attempt, even with the assistance of agency counsel, to fashion a valid regulation from the remnants of the old rule." *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006). HHS asserts that "portions of the Rule can clearly operate independently from each other," Def. Opp. 33, but does not explain how severing any portion of the Rule would "leave a sensible regulation in place." *MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 253 F.3d 732, 735 (D.C. Cir. 2001). Maintaining only part of the Rule would be particularly ill-advised in light of the threat of "confusion" about the Federal Conscience Statutes. Def. Opp. 16.

CONCLUSION

The City requests that the Court vacate and set aside the Rule before November 22, 2019 or, if necessary, preliminarily enjoin the Rule pending resolution of the merits.

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Respectfully submitted,

By: */s/ Suzanne Sangree*

Andre M Davis #00362
Baltimore City Solicitor
Suzanne Sangree #26130
Senior Public Safety Counsel and
Director of Affirmative Litigation
Jane Lewis #20981
Assistant Solicitor
BALTIMORE CITY
DEPARTMENT OF LAW
City Hall, Room 109
100 N. Holliday Street Baltimore, MD 21202
Tel: (443) 388-2190
andre.davis@baltimorecity.gov
suzanne.sangree2@baltimorecity.gov

Arun Subramanian (*admitted pro hac vice*)
Seth Ard (*admitted pro hac vice*)
Elisha Barron (*admitted pro hac vice*)
Ryan C. Kirkpatrick (*admitted pro hac vice*)
SUSMAN GODFREY L.L.P.
1301 Avenue of the Americas, 32nd Fl
New York, New York 10019
Tel.: (212) 336-8330
asubramanian@susmangodfrey.com
sard@susmangodfrey.com
ebarron@susmangodfrey.com
rkirkpatrick@susmangodfrey.com

Daniel J. Shih (*admitted pro hac vice*)
SUSMAN GODFREY L.L.P.
1201 Third Avenue, Suite 3800
Seattle, Washington 98101
Tel.: (206) 516-3880
dshih@susmangodfrey.com

Richard B. Katskee #27636
Kenneth D. Upton, Jr. (admitted pro hac vice)[18]
AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234
katskee@au.org
upton@au.org

ATTORNEYS FOR PLAINTIFF

[18] Admitted in Texas and Oklahoma only. Supervised by Richard B. Katskee, a member of the D.C. Bar.

CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2019 the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system and all counsel of record will receive an electronic copy via the Court's CM/ECF system.

/s/ Elisha B. Barron
Elisha B. Barron